DETAILED ACTION

Receipt is acknowledged of applicant's Amendment/Remarks filed 5/10/2010 and 6/23/2010.

Claims 1, 3-14 and 16-18 are pending. Claim 1 has been amended. Claims 2 and 15 have been cancelled. Claims 6-14 and 16-18 are withdrawn. Thus, claims 1 and 3-5 are currently under consideration.

WITHDRAWN REJECTIONS

Applicant's amendment renders the rejection(s) under 35 USC 102 over references Kim et al. (WO 99/20745 A1) and Fox et al. (USPN 5,360,614) moot. Both references appear to teach compositions that degrade in the intestines. The intestines have a much higher pH than the claimed pH range of 1.5 to 2 in the instant claims. Thus, said rejections have been withdrawn.

Rejections and/or objections not reiterated from previous Office Action(s) are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

MAINTAINED REJECTIONS

The following rejections have been maintained from the previous Office Action dated 3/12/2010:

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3 and 5 are rejected under 35 U.S.C. 102(b) as being anticipated by Katzen (USPN 3,962,416, hereinafter as “Katzen”).

Katzen teaches a nutrient in particulate form encapsulated by an agent such as wheat gluten flour (claim 1). It is noted that “wheat gluten flour” taught by Katzen reads on the claimed “wheat protein derivatives”. Katzen defines “nutrient” to include hormones, enzymes, pigments, lipids, plasma proteins, inorganic salts, vitamins (col. 2, lines 31-34). No animal protein is present in the encapsulating agent, thus reading on "less than 1%" in claim 5 (Example 6).

Katzen is silent to the limitations regarding the solubility parameters of the coating, however Katzen teaches the same materials as claimed. A composition and its properties are inseparable. *See* MPEP § 2112.01. The solubility properties of the coating depend upon the composition itself and Katzen teaches the composition as claimed, therefore Katzen’s composition inherently possesses the same claimed properties. Thus, the instant claims are anticipated.

Response to Arguments

Applicant's arguments filed 5/10/2010 and 6/23/2010 have been fully considered but they are not persuasive.

Applicant argues that Katzen does not teach the limitations regarding solubility of the coating. Applicant also argues that Katzen does not teach that protein source is selected from vital wheat gluten, wheat protein isolate, wheat protein derivatives, soy protein, or mixtures thereof. *See* page 7 of Remarks.

In response, it is respectfully submitted that Katzen teaches wheat flour and wheat gluten flour which reads on the claimed "wheat protein derivatives". "Derivative" is a broad limitation and without a clear definition can be broadly interpreted to include wheat flour or wheat gluten flour. Regarding the solubility limitations, said limitations are based on the coating composition itself. Katzen teaches the same composition as claimed. A composition and its properties are inseparable (MPEP § 2112.01). Thus, one of ordinary skill in the art would expect the composition of Katzen to possess the same properties as the claimed invention.

Thus, for these reasons, Applicant's arguments are found unpersuasive. Said rejection is maintained.

NEW REJECTIONS

In light of applicant's amendments, the following rejections have been newly added:

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1 and 3-5 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for vital wheat gluten and wheat protein isolate solubilizing in a pH range of 1.5 to 2, does not reasonably provide enablement for soy protein solubilizing in a pH range of 1.5 to 2. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

Enablement is considered in view of the Wands factors (MPEP 2164.01 (a)). These include: (1) breadth of the claims; (2) nature of the invention; (3) state of the prior art; (4) amount of direction provided by the inventor; (5) the level of predictability in the art; (6) the existence of working examples; (7) quantity of experimentation needed to make or use the invention based on the content of the disclosure; and (8) relative skill in the art. All of the factors have been considered with regard to the claim, with the most relevant factors discussed below:

1) The breadth of claims: Claim 1 is directed to an encapsulated comestible material comprising at least one comestible particulate material and a coating composition, said coating composition comprises a plant-derived protein source selected from the group consisting of vital wheat gluten, wheat protein isolate, wheat protein derivatives, soy protein and mixtures thereof, wherein said coating composition

is substantially insoluble in the rumen of an animal and said coating composition solubilizes in an environment having a pH in the range of from 1.5 to 2.

2) The nature of the invention: The invention is drawn to an encapsulated composition for rumen animals which is able to pass through the rumen without solubilizing and then solubilize later in the digestive tract where the pH is between 1.5 and 2.

3) The state of the prior art: The state of the art is very high in terms of compositions comprising a particulate material and a coating containing the claimed plant-derived protein sources (e.g., USPN 3,962,416 and USPN 3,314,800). However, there is no evidence in the prior art that soy protein would be able to solubilize in an environment with a pH of 1.5 to 2. In fact, the art teaches that soy protein products (i.e., soy protein isolates) can have variable solubility and suggests that their solubility properties are dependent on their protein subunit composition (*see* Lee et al. "Protein Solubility Characteristics of Commercial Soy Protein Products", page 86, col.2). Lee et al. also teaches that native soy protein is highly soluble at alkaline pH levels (page 86, col. 2, lines 18-21) which is contrary to the acidic pH range being claimed in the instant application.

4) The amount of direction provided by the inventor: There is nothing in the specification that would indicate that wheat protein derivatives or soy protein, in particular, will solubilize in an environment that has pH range of 1.5 to 2. Guidance for coatings containing wheat gluten and wheat protein isolate that solubilize in environments with a pH range of 1.5 to 2 is provided in the specification (*see*

Examples). Although coatings containing wheat gluten or wheat protein isolate are capable of solubilizing in environments with a pH of 1.5 to 2, there is nothing in the specification that indicates that coatings containing other proteins such as wheat protein derivatives or soy protein have the same solubility properties. As such, there is a substantial gap between coatings containing wheat gluten or wheat protein isolate and coatings containing wheat protein derivatives or soy protein. Consequently, a burdensome amount of research would be required by one of ordinary skill in the art to bridge this gap.

5) Predictability of the art: The prior does not teach a coating comprising wheat protein derivatives or soy protein that solubilizes at a pH of 1.5 to 2. In fact, the prior art teaches away from such coatings as discussed *supra*.

6) The presence or absence of working examples: Applicant describes examples in the instant specification; however it is directed toward coatings comprising wheat gluten and wheat protein isolate, not coatings comprising wheat derivatives or soy protein. Overall, applicant fails to provide examples indicating that the instant composition containing the claimed proteins can all solubilize in a pH environment of 1.5 to 2. What is provided in the specification is a composition comprising a coating comprising wheat gluten or wheat protein isolate wherein said coating can solubilize in an environment having a pH of 1.5 to 2. Therefore, the practitioner would turn to trial and error experimentation to make/use the instant compositions with the solubility properties claimed, without guidance from the specification or the prior art.

7) The quantity of experimentation: In the instant case, there is a substantial gap between coatings containing wheat gluten or wheat protein isolate and coating containing wheat derivatives or soy protein because of the difference in solubility properties. Consequently, a burdensome amount of research would be required by one of ordinary skill in the art to bridge this gap. In order to utilize the composition as claimed, the skilled artisan would be presented with an unpredictable amount of experimentation. An undetermined number of experimental factors utilizing said composition with the solubility properties claimed would have to be resolved by the artisan for the following reasons. The factors are not sufficiently discussed in the specification to provide guidance to utilize the invention as claimed and the teachings in the art are completely repugnant to the broad scope of the claimed composition.

8) The relative skill of those in the art: the skill of one of ordinary skill in the art is very high, e.g., Ph.D. and M.D. level technology.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 3-5 are rejected under 35 U.S.C. 102(b) as being anticipated by Noznick et al. (USPN 3,314,800, hereinafter as “Noznick”).

Noznick teaches dry roasted peanuts that are coated with a composition comprising vital wheat gluten (col. 1, lines 41-43). It is noted that peanuts are broadly and reasonably interpreted to read on the claimed limitation "comestible particulate material'. Regarding instant claim 3, it is also noted that peanuts are made up of protein, vitamins, minerals, amino acids, and so on. Regarding instant claims 4 and 5, the coating composition may contain 5-50% vital wheat gluten and no animal protein is present which reads on “less than 1% by weight animal protein” in instant claim 5 (col. 4, lines 45-50).

Noznick is silent to the limitations regarding the solubility parameters of the coating, however Noznick teaches the same materials as claimed. A composition and its properties are inseparable. *See* MPEP § 2112.01. The solubility properties of the coating depend upon the composition itself and Noznick teaches the composition as claimed, therefore Noznick’s composition inherently possesses the same claimed properties. Thus, the instant claims are anticipated.

Conclusion

All claims have been rejected; no claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Casey Hagopian whose telephone number is 571-272-6097. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert A. Wax, can be reached at 571-272-0623. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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